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Does Evidence Drive Pharmacist Over-the-Counter Product
Recommendations?

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Abstract

Aims and Objectives

To explore how community pharmacists use evidence to inform their practice when recommending or selling over-the-counter medicines.

Methods

Semi-structured face-to-face interviews were conducted during February 2013 and analysed using the principles of content analysis.

Results

Sixteen pharmacists were interviewed. Pharmacists were aware of evidence based medicine and practice but relied on personal judgement augmented with patient feedback to make product recommendations. This was primarily due to the acknowledgement that many non-prescription medicines either had no or little evidence of efficacy. Pharmacists did and would use evidence to inform product selection if available but acknowledged that ineffective products were sold, especially when consumers asked for a named product. This was tempered by their attempts to inform the consumer of the products effectiveness, or lack of, or in the knowledge that it would cause them no harm.

Conclusions

Pharmacists took a pragmatic approach to product recommendation in light of the lack of clinical evidence to support their efficacy.

Introduction

The global market for over-the-counter (referred to here in as non-prescription) medicines is very considerable and rising with annual sales growth now outstripping that of prescription medicines [1]. For example, in 2011, the UK market was worth £2.3 billion [2] and in the United States customers spent \$17 billion in 2010 – a rise of over \$3 billion over the preceding 10 years [3].

A combination of factors has fuelled this world-wide increase in non-prescription sales. These include government health care policies that encourage self-care and self-medication coupled with a greater emphasis on cost containment by health care organisations [4-5]. At the same time there has been an unprecedented rise in the number of medicines deregulated from prescription only control to non-prescription status [6-7].

In the UK numerous health policy papers have been published detailing how maximising self-care can be achieved [8-12], with the contribution from community pharmacy being specifically highlighted [13-15]. Additionally, over 80 medicines have now been switched from prescription to non-prescription status since the first occurred in 1983 [16]. Pharmacists can now sell or recommend a plethora of medicines ranging from traditional remedies that have been on the market for many years to recent prescription medicines, such as proton pump inhibitors or statins. These recent 'switches' are assessed on the basis of safety profile and efficacy, although efficacy is

usually drawn from data through prescription use rather than the intended non-prescription use.

Over this period the practice of evidence-based medicine (EBM) has become firmly embedded in Western healthcare and is considered the gold standard by which all diagnostic and therapeutic interventions are judged. An evidence based approach can be defined as *'the conscious, explicit and judicious use of current based evidence in making decisions about the care of individual patients'* [17]. EBM is now part of degree syllabus for pharmacists across the globe, and recognised by the World Health Organisation [18].

Despite the upward sales trend for non-prescription medicines and governments' continued promotion of self-care, to date little attention has been paid on how community pharmacists use evidence to inform practice when selling or recommending non-prescription medicines. Just one recent study by Hanna et al in Northern Ireland investigated what influenced non-prescription product recommendations. They found that product safety rather than evidence was the most important factor considered by pharmacists [19]. This study's aim was to explore how evidence was used (if at all) and to determine if safety, as shown by Hanna et al, was also the predominant factor in pharmacist choice.

Method

Semi-structured face-to-face interviews were conducted with 16 pharmacists working from pharmacies in the West Midlands, England. Pharmacists belonging to the 'Black Country' local practice forum (covering the administrative and geographical areas of Dudley, Sandwell, Walsall and Wolverhampton) were sent information about the study. Those that expressed an interest in the study were then telephoned to arrange a suitable time and place for the interview to take place. This sampling strategy only yielded four participants. Subsequently convenience and snowball sampling was used to ensure sufficient participants to allow data saturation to be reached.

Prior to the interview, assurances were given over anonymity and confidentiality. Interviews were performed by EW at each pharmacist's place of work. On the day of the interview participants were reminded of the purpose of the study and had the opportunity to ask questions before giving written consent. The interview schedule was developed by EW and drew on findings from work by Hanna [19].

Questions were open-ended and explored how pharmacists used evidence of non-prescription products in patient consultations. The interview schedule was piloted on three pharmacists and showed that minor changes to wording were required to aid clarity and facilitated an interview of approximately 10 to 20 minutes' duration. Interviews took place in February 2013.

Interviews were audio recorded and transcribed *verbatim*. Nvivo software (QSR International Pty Ltd, UK) was used to manage the data and content analysis was used to identify any emergent themes; these were validated for context and understanding by a second member of the research team (PR).

To assess participant validity, the first five transcripts were returned to participants to check that their individual opinions had been accurately represented. With regard to reflexivity, the interviewer (EW) had no relationship to any of the pharmacies or staff where interviews were conducted.

Ethical approval was granted by The Behavioural Sciences Ethics Committee, University of Wolverhampton.

Results

Sixteen community pharmacists participated in the study; nine were women and seven were men. The majority were employee pharmacists working for large national multiple chain pharmacies, although some were owners of their own pharmacy. It was clear that community pharmacists had a good understanding of the concept of EBM yet opportunities to exercise this approach when recommending non-prescription products was limited. All but one pharmacist stated that the lack of evidence associated with products was the primary reason:

'There is not much evidence out there. I know when I started I was like I am always going to give the best thing out there...It's much easier with prescription medicines than it is with over-the-counter...over-the-counter, it's all shiny boxes.' (CP4)

'Most of the old products don't have any evidence. No one proved that they are effective but they are still used. Some of the evidence of the new products is not very clear.' (CP15)

'The evidence base of over-the-counter is sometimes questionable.' (CP3)

Because they were aware that many non-prescription products had either no or little evidence of efficacy they made decisions based on a combination of

factors that included, patient safety, risk minimisation, pharmacological action of medicine, placebo effect and personal experience/judgement:

'My first priority as a pharmacist is their (the patient) safety.' (CP7)

'I use what I know from experience, feedback from patients, active ingredients, yeah that's good enough.' (CP12)

'As long as it's not posing a risk to the patient I do not see the reason why we should not. I mean a lot of the products have no evidence so I see why people just recommend products using their own expertise.' (CP13)

'I look at the active ingredients. I also usually recommend what I have used before so yeah pretty much personal experience'. (CP6)

'I do have a number of patients that just walk in and want me to give them medications for conditions that do not need any treatment. It's a psychological thing to be honest. They buy it in the belief that it works and it works for them, the placebo effect cannot be underestimated.' (CP10)

Personal experience/judgement appeared to have the greatest influence on decision making and was reinforced by patient/customer feedback, exemplified by the following comments:

'Your experience will help you judge what actually works and what doesn't. I also get to ask my patients on whether the products worked and this also helps.' (CP15)

'There is not that much information out there anywhere and the little that is published is not that clear as well. I am left with no choice but to use my personal judgment based on patients' experiences and other factors to come up with decisions.' (CP15)

Pharmacists did acknowledge that they sold products to people where evidence was lacking, especially if patients/customers insisted on a particular product. However, all stated they would try to explain to the person the lack of evidence of the requested product(s).

'When parents ask for something for a cough for their child, I tell them that it will go away on its own and tell them to give the child plenty of fluids and rest...but if you want it and think that it will help soothe the throat then you can take it. It will not make the cough any better because there is no evidence to show that its effective.' (CP3)

'There are a number of times I have said to people...yeah you are welcome to buy that because it does not do you any harm but I generally don't think it will do you good either. I wouldn't waste your money.' (CP4)

The need to explain to the person seemed rooted in their professional values:

The public puts so much trust in us. By recommending some product when you know it does not work is just like grabbing money out of their wallets. It's just not right.' (CP16)

'If someone has got a blood shot eye because they have sub-conjunctival haemorrhage that will get better by itself, I would not give them anything. I won't just sell themDrug XXX when I know it's not going to work.' (CP6)

'It's not professional to sell things like cough and cold remedies without even bothering to inform the patient that they don't do any good.' (CP8)

Pharmacists were prepared to alter their practice if new or credible evidence became available:

'I don't mind changing my practice to suit new evidence. If it turns out something is not as effective as I thought and a proven product comes out, I definitely use that.' (CP12)

'I don't have a problem with changing my practice to suite evidence because evidence changes all the time.' (CP4)

Pharmacists spoke about being put under pressure to sell products to patients and commented on direct to consumer advertising being influential in shaping patient product choice.

'The fact that companies heavily advertise some products, patients just turn up with specific product requests not symptoms and no matter what you say they will not change their minds.' (CP9)

Even if you try and convince them to buy a more effective product they will just end up buying what they came in to buy in the first place. I blame most of this on adverts. (CP13)

Commercial pressure also had an influence on pharmacists, with both owners of pharmacies and employees of multiple chains speaking of financial pressures impacting on what products were supplied.

'We are sometimes told to try and push sales of certain products because the company gets them cheap from manufacturers.' (CP2)

'Recommending an ineffective product is not ethical and not professional. Selling products, on the other hand is different. Some patients will insist on buying the product. Like I said, it's a business for me, this is what pays my bills and I am not going to refuse to sell because no study was done on the product to prove its' efficacy.' (CP11)

Discussion

Evidence of efficacy was not the key determinant for selection of non-prescription products by community pharmacists in this study. This was primarily as a result of the lack of evidence associated with non-prescription products. Pharmacists were mindful that old products that pre-dated the requirement for licensure had no empirical evidence to substantiate claims and even those products recently switched from prescription control to non-prescription use, at times, the evidence was questionable. This stance is grounded in fact [16].

Pharmacists therefore tended to make decisions based on personal experience that was shaped by patient feedback in addition to the products ability to cause no harm. This latter finding is consistent with the findings of Hanna et al, although appeared to be less influential in the community pharmacist's decision to supply products [19]. Pharmacists also spoke of utilising theoretical pharmacological action of medicines to substantiate a product recommendation and recognised the placebo effect associated with non-prescription medicines – both of these approaches are grounded in the principles of their scientific training. This may suggest that although personal judgment was relied upon, they were attempting to rationalise this from a scientific stance.

Pharmacists were willing to accept new evidence (whether this be efficacy or safety data) to inform and change their practice, with more than one pharmacist citing recent Medicine and Healthcare Products Regulatory Agency advice (UK body regulating supply of medicines). This highlights that when robust and reliable information is provided, community pharmacists will act upon it and make product recommendations based on evidence. It was clear that pharmacists were uncomfortable in recommending products that had no evidence of efficacy. This was seen as something that challenged their professional ethics and devalued their role as a community pharmacist and contravened the principles of their code of conduct [20]. Yet, most pharmacists spoke of selling such products. This appeared to be in the context of people asking for products by name, and in such circumstances pharmacists did state they would explain to the patient the product's effectiveness (or lack of), and again aligns with a professional sense of duty. Pharmacists spoke about trying to dissuade people from buying ineffective products, yet acknowledging this was often unsuccessful - in these circumstances it appeared that pharmacists felt under pressure to supply and avoided conflict in the knowledge that the product was going to be safe for the person to use. In part, the situation may have arisen because of direct to consumer advertising, and has been noted by Chaar et al as disempowering pharmacists in non-prescription product selections [21]. Further work is needed to explore this consumer/pharmacist relationship in the context of optimising care.

Pressure also came in the form of commercial targets and the necessity to 'make a living'. This commercial-professional conflict has, and will always continue to be, an aspect of a profit-driven enterprise such as community pharmacy. What came through from this study was that those interviewed were cognisant of this fact. A pharmacy could choose not to stock products with no evidence of efficacy, but this would potentially put them at a commercial disadvantage to others, and without legislation mandating this, this seems highly unlikely to happen.

Given EBM is now a cornerstone of medical practice, where do non-prescription medicines fit with symptom management and the self-care agenda? Realistically, without non-prescription medicines and people exercising self-care primary healthcare systems would become overloaded and unable to cope [22]. It appears that from this study, community pharmacists are adopting the principles of EBM where they can but are required to adopt a pragmatic approach to product recommendation in the absence of evidence. This study did have some limitations. First, the participants may not be representative of all community pharmacists practicing in England as only one geographic (urban) area of England was used to draw the sample and contained only employees or owners. The findings centred on commercial pressures may therefore be over-represented due to the absence of self-employed pharmacists. Second, the sampling strategy used may have introduced bias as those interviewed may have stronger opinion toward non-prescription products.

Conclusion

Community pharmacists generally used personal judgment based on experience and anecdotal evidence to select non-prescription products due to the lack of credible evidence associated with them.

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